

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

HORIZON MEDICINES, LLC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. 18-1014-RGA
	:	
ALKEM LABORATORIES, LTD.,	:	
	:	
Defendant.	:	

**ORDER AFTER PRETRIAL CONFERENCE**

Now, this 31<sup>st</sup> day of August, 2020, after a pretrial conference on August 21, 2020, and upon consideration of the proposed pretrial order (D.I. 189) and the discussion at the pretrial conference, and with consideration of follow-up letters and exhibits (D.I. 193-96; D.I. 200), IT IS HEREBY ORDERED that:

1. The Proposed Pretrial Order (D.I. 189) is **ADOPTED** as modified by any discussion at the pretrial conference and in this Order.
2. A bench trial will begin on September 14, 2020, at 8:30 a.m. Each party should be prepared to present its case until 5:00 p.m. of each trial day, although the end of the trial day may, in the discretion of the Court, be earlier than 5:00 p.m.
3. The trial is timed. Each side is allowed 10 ½ hours for its opening statement and its direct and cross-examination of witnesses.<sup>1</sup> Time during the trial day that does not neatly fit into one of those categories will be attributed to one side or the other as the Court thinks most

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<sup>1</sup> The record identifies that some witnesses will testify live but remotely. If the remote procedure causes delay, as it might, the Court will extend the hours or minutes as it thinks appropriate. The parties should advise the Court during the trial if they think there is non-obvious delay occurring because of the remote procedure.

appropriate. The amount of time allowed for closing argument (if the parties want it)<sup>2</sup> will be decided during trial, and the closing argument will most likely be scheduled for September 17, 2020, either late morning or early afternoon.

4. Trial counsel (limited to two attorneys per side, with no substitutions) are to be present and ready to proceed at 8:00 a.m. each and every day of trial. There will be an hour for lunch and a fifteen-minute break in both the morning and the afternoon.

5. There were three motions in limine. I addressed them in an earlier order. (D.I. 190). At the pretrial conference, relating to Plaintiff's MIL, I think there was an agreement on reduction of claims and invalidity defenses, which may have been impacted by the subsequent decision of Plaintiff not to pursue its infringement case on the '451 patent. (*See id.*; D.I. 200). My notes indicate that process would be completed on September 2. The parties are requested to provide a status report on that process the day after it is completed. Defendant's MIL #1 was resolved in the earlier order. I will address Defendant's MIL #2 by a separate order to follow.

6. One issue that I did not resolve at the pretrial conference was Plaintiff's request to add a cause of action for correction of inventorship pursuant to 35 U.S.C. § 256. I received supplemental materials relating to that issue. (D.I. 193-96). Plaintiff wants to add Barry L. Golombik as an inventor to the '033 patent. The sixteen claims of that patent are directed to pharmaceutical compositions of ibuprofen and famotidine. Mr. Golombik is a businessman with a 1981 undergraduate degree in business and finance. (D.I. 194-1 at 13:14-17). He undertook no graduate studies. (*Id.* at 13:25-14:2). He was deposed in his personal capacity and as a Rule 30(b)(6) witness. (*Id.* at 9:6-13). He stated that he is "not a scientist" and doesn't have a

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<sup>2</sup> I generally find it helpful to have short non-Power Point closing argument in ANDA trials following the testimony. I note that I am also expecting what I called "super-expedited post-trial briefing" in light of the imminent expiration of the thirty-month stay.

“science background.” (*Id.* at 21:6-8; *see also id.* at 72:2). A frequent response to questions during the deposition referred to the questioner to Dr. Tidmarsh for an answer. (*Id.* at 38:10-14; 45:5-13; 51:15-25; 119:5-12; 134:13-22; 135:24-136:4; 169:7-23). At one point, Defendant’s counsel asked about inventorship, as follows: “Q. Do you have an understanding why Mike Li is not a named inventor on the patents? A. I don’t know. Q. Do you have an understanding why you’re not a named inventor of the ‘033 Patent? A. I was not involved in the work that was done, especially around the surface area and the geometry work.” (*Id.* at 163:4-11). It is true that there are times in the deposition where Mr. Golombik talked about “we did this,” or “we theorized that,” but he was often talking about what Horizon did or about a powerpoint presentation for investors that he had prepared jointly with Dr. Tidmarsh. In short, there’s nothing in the deposition that suggests Mr. Golombik should be a named inventor.

I am not going to allow Plaintiff to add an inventorship count at this late date. The deadline for amending pleadings was, by court order, October 8, 2019. (D.I. 21 at ¶ 2). Plaintiff needs good cause to amend after that deadline. *See* Fed. R. Civ. P. 16(b)(4); *Premier Comp Solutions, LLC v. UPMC*, \_\_\_ F.3d \_\_\_, 2020 WL 4668235, at \*2 (3d Cir. Aug. 12, 2020) (“good cause” “depends in part on a plaintiff’s diligence”). Plaintiff’s first suggestion that it wanted to amend the pleadings was on August 11, 2020 (D.I. 193 at 3), approximately one month before trial. Plaintiff offers no support for the idea that it has been diligent. There has been no discovery of new evidence. Plaintiff has simply come up with a new idea while getting ready for trial. That is not sufficient. I further note that based on the record before me, including Mr. Golombik’s deposition and what is in the pretrial order, there is no basis to believe that there has been any discovery on the issue of Mr. Golombik’s inventorship, which, of course, makes sense because it has not been an issue in the case.

7. Any trial logistics should be coordinated through the Courtroom Deputy.

/s/ Richard G. Andrews  
United States District Judge